§ 158.2200

- (e) Test notes. The following test notes are applicable to the data requirements for microbial pesticides nontarget organism and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.
- 1. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, production volume, and other pertinent factors. Tests to support EUP's are based on the application timing and acreage.
- 2. The preferred species for the avian oral study is either the upland game or waterfowl. The preferred species for the avian inhalation toxicity/pathogenicity study and the avian chronic toxicity/pathogenicity study is the upland game. There is also the option to test a passerine species if there is a concern. The coldwater fish is preferred for freshwater fish testing. However, two species (coldwater and warmwater fish are the preferred species) must be tested for uses involving direct freshwater exposure. Freshwater invertebrates are preferred for invertebrate testing.
- 3. Required when there will be significant exposure to aquatic organisms (fish and invertebrates).
- 4. Required if the microbial pesticide is taxonomically related to a known plant pathogen.
- 5. Data are not required unless an active microbial ingredient controls the target insect pest by a mechanism of infectivity; *i.e.*, may create an epizootic condition in nontarget insects.

Subpart W—Antimicrobial Pesticide Data Requirements

SOURCE: 78 FR 26978, May 8, 2013, unless otherwise noted.

EFFECTIVE DATE NOTE: At 78 FR 26978, May 8, 2013, subpart W, consisting of §§158.2200 through 158.2290 was added, effective July 8, 2013

§ 158.2200 Applicability.

Part 158, subpart W establishes data requirements for any pesticide product that is:

(a) A pesticide that is intended for use as an "antimicrobial pesticide" within the meaning of FIFRA sec. 2(mm)(1)(A), regardless of whether it also meets the criterion of FIFRA sec 2(mm)(1)(B). That criterion excludes from the definition any antimicrobial product that is intended for a food-use requiring a tolerance or exemption

under FFDCA sec. 408 or a food additive regulation or clearance under FFDCA sec. 409. EPA will apply this subpart to all products intended for an antimicrobial use, purpose or function; the exclusion in FIFRA sec. 2(mm)(1)(B) does not exclude products from the data requirements of this subpart.

- (b) A product that bears both antimicrobial and non-antimicrobial uses or claims. Such a product is subject to the data requirements for pesticides in subparts C through O, and U or V of this part with respect to its non-antimicrobial uses and claims, and to the requirements of this subpart with respect to its antimicrobial uses and claims.
- (c) A wood preservative, including a product that is intended to prevent wood degradation problems due to fungal rot or decay, sapstain, or molds.
- (d) An antifoulant, including a product that is intended to kill or repel organisms that can attach to underwater surfaces, such as boat bottoms.

§158.2201 Antimicrobial use patterns.

- (a) Antimicrobial use patterns. The 12 general use patterns used in the data tables in this subpart are:
- (1) Agricultural premises and equipment.
- (2) Food-handling/storage establishments, premises and equipment.
- (3) Commercial, institutional and industrial premises and equipment.
- (4) Residential and public access premises.
- (5) Medical premises and equipment.
- (6) Human drinking water systems.
- (7) Materials preservatives.
- (8) Industrial processes and water systems.
 - (9) Antifoulant paints and coatings.
 - (10) Wood preservatives.
 - (11) Swimming pools.
 - (12) Aquatic areas.
- (b) Use site index. The Pesticide Use Site Index for Antimicrobial Pesticides is a comprehensive list of specific antimicrobial use sites. The Index associates antimicrobial use sites with one or more of the 12 antimicrobial use patterns. It is to be used in conjunction with the data tables in this subpart to